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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,582	10/31/2006	Stefan Golz	004974.01114	6828
22907	7590	01/29/2008		
BANNER & WITCOFF, LTD. 1100 13th STREET, N.W. SUITE 1200 WASHINGTON, DC 20005-4051			EXAMINER FRONDA, CHRISTIAN L	
			ART UNIT 1652	PAPER NUMBER
			MAIL DATE 01/29/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/573,582

Applicant(s)

GOLZ ET AL.

Examiner

Christian L. Fronda

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 42-73 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 42-73 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

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**DETAILED ACTION**

***Election/Restriction***

The previous restriction requirement dated 11/02/2007 has been withdrawn in favor of the instant restriction requirement.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

- Invention 1     Claims 42, 46, 71, 72, drawn to an isolated nucleic acid molecule encoding a protein, an expression vector, a host cell transformed with said vector, and method for producing a MGAT-X2 polypeptide.
- Invention 2     Claims 43 and 73, drawn to a purified polypeptide.
- Invention 3     Claims 47 and 48, drawn to a method for detection of a nucleic acid molecule encoding a MGAT-X2 in a sample.
- Invention 4     Claim 49, drawn to a method for detection of a nucleic acid molecule encoding a MGAT-X1 in a sample.
- Invention 5     Claim 50, drawn to a method for detection of a polypeptide having MGAT-X2 activity comprising contacting a sample with a reagent which specifically interacts with said polypeptide.

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- Invention 6     Claims 51-59, drawn to a method for screening for regulators of the activity of a MGAT-X2 comprising contacting with a test compound and detecting binding of said test compound.
- Invention 7     Claims 60-63, drawn to a method for screening for regulators of the activity of a MGAT-X2 comprising measuring the activity of said MGAT-X2 in presence or absence of a test compound.
- Invention 8     Claims 64-69, drawn to a method for screening for regulators of the activity of a MGAT-X1 comprising contacting a sample with a test compound and detecting binding of the test compound.
- Invention 9     Claim 70, drawn to a method of diagnosing an MGAT-X2 related disease in a diseased mammal.

The inventions listed as Inventions 1-9 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A same or corresponding technical feature shared among Inventions 1-9 is polypeptide comprising the sequence of SEQ ID NO: 2. However, the reference of WO 03/053363 (published 07/03/2003; PTO 1449 from IDS filed 10/31/2006) teaches such a polypeptide comprising the amino acid sequence of SEQ ID NO: 20 which is 100% identical to SEQ ID NO: 2 of the instant application, and inherently has MGAT-X2 activity because of its 100% identity to SEQ ID NO: 2. See entire publication and alignment below.

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Alignment of reference SEQ ID NO: 20 to SEQ ID NO: 2 of instant application

Aligned sequences: 2

1: SEQ ID NO: 20 of WO 03/053363

2: SEQ ID NO: 2

Matrix: EBLOSUM62

Gap\_penalty: 10.0

Extend\_penalty: 0.5

Length: 337

Identity: 337/337 (100.0%)

Similarity: 337/337 (100.0%)

Gaps: 0/337 (0.0%)

Score: 1802.0

SEQ ID NO: 20	1	MAFFSRLNLQEGLOTFFVLQWIPVYIFLGAIPILLIPYFLLFSKFWPLAV	50
SEQ ID NO: 2	1	MAFFSRLNLQEGLOTFFVLQWIPVYIFLGAIPILLIPYFLLFSKFWPLAV	50
SEQ ID NO: 20	51	LSLAWLTYDWNTHSQGGRRSAWVRNWLWKYFRNYFPVKLVKTHDLSPKH	100
SEQ ID NO: 2	51	LSLAWLTYDWNTHSQGGRRSAWVRNWLWKYFRNYFPVKLVKTHDLSPKH	100
SEQ ID NO: 20	101	NYIIANHPHGILSFGVFINFATEATGIARIFPSITPFVGTLERIFWIPIV	150
SEQ ID NO: 2	101	NYIIANHPHGILSFGVFINFATEATGIARIFPSITPFVGTLERIFWIPIV	150
SEQ ID NO: 20	151	REYVMSMGVCPVSSSALKYLLTQKGSNAVVI VVGAAEALLCRPGASTL	200
SEQ ID NO: 2	151	REYVMSMGVCPVSSSALKYLLTQKGSNAVVI VVGAAEALLCRPGASTL	200
SEQ ID NO: 20	201	FLKQRKGFVKMALQTGAYLVPSYSFGENEVFNQETFPEGTWLRFLQKTFQ	250
SEQ ID NO: 2	201	FLKQRKGFVKMALQTGAYLVPSYSFGENEVFNQETFPEGTWLRFLQKTFQ	250
SEQ ID NO: 20	251	DTFKKILGLNFCTFHGRGFTRGSWGFLPFNRPITTVVGEPLPIPRIKRPN	300
SEQ ID NO: 2	251	DTFKKILGLNFCTFHGRGFTRGSWGFLPFNRPITTVVGEPLPIPRIKRPN	300
SEQ ID NO: 20	301	QKTVDKYHALYISALRKLFQHKVEYGLPETQELTIT	337
SEQ ID NO: 2	301	QKTVDKYHALYISALRKLFQHKVEYGLPETQELTIT	337

Thus, the same or corresponding technical feature is not special since it was known in the prior art and therefore cannot make a contribution over the prior art. Since the inventions lack

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the same or corresponding special technical feature, then the inventions listed as Inventions 1-9 are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121

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does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272 0929. The examiner can normally be reached Monday-Thursday and alternate Fridays between 9:00AM 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272 0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

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like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christian L. Fronda/

Patent Examiner

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